X. 510 (k) Summary

NOV 0 7 2001

SUBMITTER: DePuy AcroMed™, Inc.
325 Paramount Drive
Raynham, MA 02780

CONTACT PERSON: Karen F. Jurczak

DATE PREPARED: September 26, 2001

CLASSIFICATION NAME: Appliance, Fixation, Spinal Interlaminal
Orthosis, Spinal Pedicle Fixation

PROPRIETARY NAME: Summit OCT Spinal System

PREDICATE DEVICES: Summit OCT Spinal System (K002733, K010681)
Synthes CerviFix System (K001864)

INTENDED USE: When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Summit Occipito-Cervico-Thoracic (OCT) Spinal System is indicated for:

- ddd (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- spondylolisthesis
- spinal stenosis
- fracture/dislocation
- atlantoaxial fracture with instability
- occipitocervical dislocation
- revision of previous cervical spine surgery
- tumors

The occipital bone screws are limited to occipital fixation only.

The use of the minipolyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The Songer Cable System to be used with the Summit OCT Spinal System allows for wire/cable attachment to the posterior cervical spine.

The Summit OCT System can also be linked to the ISOLA, TiMX, Monarch and MOSS Miami Systems using the dual wedding band and axial connectors, and via dual diameter rods.

MATERIALS:

Manufactured from ASTM F-136 implant grade titanium alloy.

DEVICE DESCRIPTION:

The Summit OCT Spinal System consists of plates, nuts, bone screws, rods, transverse rod connectors, cable connectors, dual wedding band and axial connectors, set screws, minipolyaxial screws and Songer Cables. For occipitocervicothoracic fusion, the transition rod is bent and cut to the appropriate length. The occipital plate is fixed to the occiput with bone screws and the transition rod is attached to the plate by a locking mechanism. This locking mechanism consists of a bolt and a washer which are free to rotate and translate along a slot in the occipital plates. The rod loads from the top and is fixed and locked into place with a mini outer nut. Sub-axially, cable connectors are fixed to the transition rod and attached to the spine via sublaminar cabling looped through the cable connectors. The end of the construct is stabilized with polyaxial screws and mini outer nuts to the upper thoracic spine, as required.

The Summit OCT System can also be linked to the ISOLA, TiMX, and MOSS Miami Systems using the dual wedding bands and axial connectors, and via dual diameter rods.

PERFORMANCE DATA:

Biomechanical testing, including static and dynamic construct axial compression bending and static construct torsion, were conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Mr. Frank Maas
Manager, Regulatory Affairs
DePuy Acromed, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K013222
Trade/Device Name: Summit Occipito-Cervico-Thoracic (OCT) Spinal System
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: MNI, KWP
Dated: September 26, 2001
Received: September 27, 2001

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use

510(k) Number (if known): K013222 NOV 0 7 2001

Device Name: Summit OCT Spinal System

Indications For Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Summit Occipito-Cervico-Thoracic (OCT) Spinal System is indicated for:

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013222